

Surgical
N95

User Instructions for DD02-N95+S Surgical N95 Respirator

(Conforming to the U.S. NIOSH Standard 42 CFR Part 84, Class N95)

(Conforming to the U.S. NIOSH Conformity Assessment Letter to Manufacturers NIOSH CA 2018-1010R1.0, Surgical N95)

October 2021

Carefully read the instructions before use to understand thoroughly the contents and to use the respirator correctly.

Keep the instructions at hand for future reference. If you lose the instructions, contact the distributor for another copy.

Definition of Warning Label

DANGER, WARNING and CAUTION described in the Instructions indicate important matters you should understand to avoid possible accidents due to misuse of the product. The respective symbols have the following meanings:

	Misuse would likely result in death or serious health hazards to the wearer.
	Misuse could cause death or serious health hazards to the wearer.
	Misuse could cause health risks or property damage to the wearer.

Special or Critical User Instructions

"S" This respirator has been approved as a NIOSH N95 filtering facepiece respirator, for use in healthcare settings, as a Surgical N95 Respirator conforming to recognized standards for biocompatibility, flammability, and fluid resistance.

Before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the local government requirements. In the United States, employers must comply with OSHA 29 CFR 1910.134 which includes medical evaluation, training, and fit testing.

Precautions for Use

Please observe the following precautions for safe use of the respirator.

Misuse may jeopardize the life of the wearer.

	<p>1. Never use the respirator under the following conditions which may result in death or serious health hazards.</p> <ul style="list-style-type: none"> In an environment where the oxygen concentration is less than 19.5 %. In an environment where contamination materials are unknown. In an environment where there is toxic gas, vapor, or oil mist. In an environment where contamination materials pose immediate danger to life or health.
	<p>2. Never use the respirator except for the specified application within the specified use range.</p> <p>1. Do not disassemble or modify the respirator.</p> <p>2. Do not wear the respirator if you are characterized by any of the following cases.</p> <ul style="list-style-type: none"> If you have beards, whiskers, etc., do not use with beards that prevent direct contact between the face and the respirator. If you have a respiratory or circulatory system disease. If you are out of shape <p>3. Be sure to conduct the prior-to-use check.</p> <p>4. Do not put anything between your face and the respirator.</p> <p>5. Remove the respirator in a safe place if any of the following occurs.</p> <ul style="list-style-type: none"> If the inhalation resistance increases. If any part is broken. If you feel your health condition is not good. <p>6. Be sure to replace the respirator with a new one when it is contaminated, damaged or deformed substantially.</p> <p>7. Do not wash the respirator, otherwise the filter efficiency may decrease.</p> <p>8. Do not blow off the dust adhered to the respirator induced by compressed air because it may cause a decrease of filter efficiency.</p> <p>9. This respirator is sensitive to shock. Do not bang or slam down the respirator because it may cause a decrease of filter efficiency.</p> <p>10. The storage period of the respirator is five (5) years from the date of manufacture in a sealed condition. Do not use the respirator after the storage period has expired.</p> <p>11. Dispose of the respirator after each use. Never reuse the respirator.</p>
	<p>1. This respirator may cause a rash, red flare, itch, or some other symptom due to an allergic reaction, hazardous substances in the environment, or sweat. In that case, stop wearing the respirator and consult with a dermatologist, etc. (Continued use may worsen the symptom.) Especially if you are allergic, stop wearing the respirator immediately when a rash, red flare, itch, or some other symptom appears.</p>

Applications and Scope of Use

The respirator is designed to protect humans from hazardous particulates or virus in environment. The respirator is approved by US NIOSH as Class N95.

Furthermore, it is authorized as Surgical N95 which is confirmed to recognized standards for biocompatibility, flammability, and fluid resistance required by US FDA.

The respirator shall not be used in the following conditions:

- In an environment where the oxygen concentration is less than 19.5 %.
- In an environment where there is toxic gas, vapor, or oil mist.

	The respirator has not obtained the national certification of Japan. Please do not use it for industrial hygiene measures in Japan.
--	--

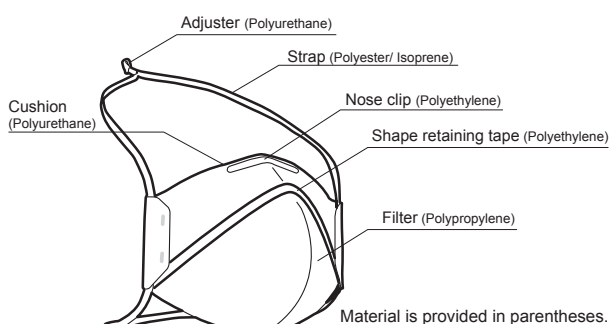
Features

- The electret filter is used to make it light in weight and compact.
- The length of the straps is adjustable so that it can be fit to any wearer.
- The respirator has no metallic part. Therefore, it does not require separation for disposal.

Performance

Item		NIOSH standard (N95)
Filter efficiency (NaCl)	[%]	95 or more
Inhalation resistance at 850/min flow	[Pa]	343 or less
Exhalation resistance at 850/min flow	[Pa]	245 or less

Structure and Name of Each Part



Check before donning

Wearer must check the following items before use.

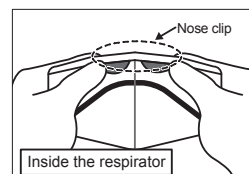
If you find any failure or defect, please replace the respirator with a new one.

- Check that the respirator is free from fissures or holes.
- Check that the respirator is not dirty.
- Check that the straps have a sufficient elasticity.

How to wear and remove the respirator

<Wearing the respirator>

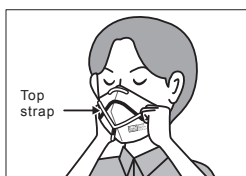
- Expand the respirator and flatten the nose clip (area enclosed in dotted line).



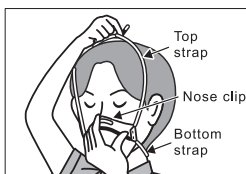
- Put the bottom strap around your neck.



- Set the top strap to the outer side of the respirator and while holding the both ends of the respirator with both hands, put the respirator over the nose and mouth.



- Hold the respirator with one hand, then put the top strap over and settle it at top back of your head with the other hand.



- Pull the adjuster for the top strap, if necessary, to adjust the length of the strap so that the respirator can be attached firmly to your face.



- Adjust the tensions of the top and bottom straps so that the respirator fits securely to your face.



- Press the nose clip with fingers of both hands so that the respirator can be attached firmly to your nose.



CAUTION Do not hold both the top and bottom straps at the same time when donning; otherwise, your face may get injured by a corner of the respirator.

<Removing the respirator>

After removing the top strap over the back of your head, remove the bottom strap hanging around your neck.



CAUTION In order to prevent the secondary infection, special care must be taken not to touch the surface of the respirator when taking off the respirator.

■ Proper fitting

In order to achieve the original performance of the respirator, the respirator must have best fit. The user is required to be fit tested according to OSHA 29 CFR 1910.134 either qualitatively or quantitatively prior to use. Conduct a fit check following this procedure every time you put on the respirator.

- Wear the respirator in the same manner as you actually conduct during work.
- Cover the respirator with two hands and exhale. If it is not possible to cover the respirator with both hands, use a polyethylene sheet to cover the surface of the respirator, holding it down with both hands and exhale.
- Check that no air leaks through respirator-to-face seal when you exhale. If you feel air leakage, adjust the position of respirator and/or tension of straps until the air leakage stops.

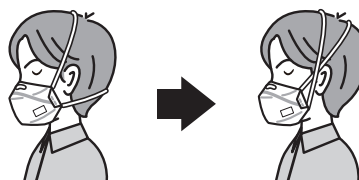


WARNING

- Before using the respirator in an actual operation, be sure to conduct the inspection whether the respirator is properly fitted or not.
- If it is not possible to ascertain that the respirator is properly fitted, do not use the respirator in an actual operation. Make the necessary adjustments so that the respirator firmly fits your face. If it is still not possible to ascertain that the respirator is attached properly after those adjustments, inspect each and every portion of the respirator at a safe place. (Please refer to "Check before donning".)

<For your reference>

If your face is too small to fit properly to your chin, it is recommended to put the bottom strap over the back of your head as shown in the figure below so that the respirator is tightly fitted around the chin.



■ Storage Method

Store the respirator in a clean, cool, dark and dry place.



CAUTION Do not pile up or bend the respirators to store ; it may cause problems such as fissures, deformation, etc.

■ Disposal Method

Put the used respirator in an airtight bag to prevent the particulate matters from scattering before disposal in accordance with the applicable laws and regulations.

■ NIOSH Approval Label



SHIGEMATSU WORKS CO., LTD.

1-26-1, Nishigahara, Kita-ku, Tokyo
114-0024, JAPAN
+81-3-6903-7525

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection ¹	Respirator	Cautions and Limitations ²
		DD02-N95+S	
84A-9373	Surgical/N95	X	ABCJMNOS

1. Protection

N95 – Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

2. Cautions and Limitations

- A- Not for use in atmospheres containing less than 19.5 % oxygen.
- B- Not for use in atmospheres immediately dangerous to life or health.
- C- Do not exceed maximum use concentrations established by regulatory standards.
- J- Failure to properly use and maintain this product could result in injury or death.
- M- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
- N- Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O- Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- S- Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

For more information regarding the handling method of the product, please contact:



SHIGEMATSU WORKS CO., LTD.

Head Office
1-26-1, Nishigahara, Kita-ku, Tokyo 114-0024, Japan
Tel : +81-3-6903-7525